AMENDED IN ASSEMBLY JUNE 17, 2004

AMENDED IN SENATE APRIL 21, 2004

AMENDED IN SENATE APRIL 12, 2004

SENATE BILL No. 1765

Introduced by Senator Sher
(Coauthors: Senators Chesbro and Kuehl)
(Coauthor: Assembly Member Koretz)

February 20, 2004

An act to add Chapter 8 (commencing with Section 119400) to Part 15 of Division 104 of the Health and Safety Code, relating to pharmaceutical marketing.

LEGISLATIVE COUNSEL'S DIGEST

SB 1765, as amended, Sher. Pharmaceuticals: marketing practices.

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices.

This bill would require a pharmaceutical company to adopt and update a Comprehensive Compliance Program that is in accordance with a related federal government publication. The bill would require the Comprehensive Compliance Program to include, among other provisions, policies on interactions with health care professionals and limits on gifts and incentives to medical or health professionals. The bill would require each pharmaceutical company to establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional, with certain exemptions.

This bill would require a pharmaceutical company to (1) annually ~~certify~~ *declare*, in writing, compliance with the Comprehensive Compliance Program and the bill, (2) make its Comprehensive Compliance Program and written acknowledgment of compliance available to the public on its Web site, and (3) provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written ~~certification~~ *declaration* of compliance may be obtained.

~~This bill would provide that it is not to be construed to create a standard for a pharmaceutical company that is less restrictive than any otherwise applicable provision of existing law.~~

The bill would require its provisions to become operative on July 1, 2005.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The trade association known as the Pharmaceutical Research and Manufacturers of America (PhRMA) has developed voluntary guidelines for pharmaceutical companies that pertain to gifts and financial incentives provided to doctors.

(b) The Office of Inspector General (OIG) within the United States Department of Health and Human Services has developed recommendations for pharmaceutical companies that pertain to gifts, financial incentives, and other matters relating to the development, manufacturing, marketing, and sales of pharmaceutical products.

(c) The PhRMA guidelines state, ''We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large.''

(d) The OIG guidelines state, ''A comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care.''

(e) It is therefore the intent of the Legislature in enacting this act to achieve the goals expressed in both the PhRMA voluntary guidelines and the OIG voluntary guidelines and to ensure greater adherence by pharmaceutical companies to both sets of existing guidelines by requiring pharmaceutical companies to adopt policies that ensure compliance with those guidelines.

SEC. 2. Chapter 8 (commencing with Section 119400) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 8. DRUG MARKETING PRACTICES

119400. The following definitions shall apply for purposes of this chapter:

(a) ''Dangerous drug'' means any drug that is unsafe for self-use and includes either of the following:

(1) Any drug that bears the legend ''Caution: federal law prohibits dispensing without prescription,'' ''Rx only,'' or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. ''Dangerous drug'' does not include labeled veterinary drugs.

(b) ''Medical or health professional'' means any of the following:

(1) A person licensed by state law to prescribe drugs for human patients.

(2) A medical student.

(3) A member of a drug formulary committee.

(c) ''Pharmaceutical company'' means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. ''Pharmaceutical company'' also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. ''Pharmaceutical company'' also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a

pharmaceutical company. ‘‘Pharmaceutical company’’ does not include a licensed pharmacist.

119402. (a) Every pharmaceutical company shall adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication ‘‘Compliance Program Guidance for Pharmaceutical Manufacturers,’’ which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). A pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision to the ‘‘Compliance Program Guidance for Pharmaceutical Manufacturers.’’

(b) Every pharmaceutical company shall include in its Comprehensive Compliance Program policies for compliance with the Pharmaceutical Research and Manufacturers of America (PhRMA) ‘‘Code on Interactions with Health Care Professionals,’’ dated July 1, 2002. The pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision of the ‘‘Code on Interactions with Health Care Professionals.’’

(c) Each pharmaceutical company shall include in its Comprehensive Compliance Program limits on gifts or incentives provided to medical or health professionals, in accordance with this chapter.

(d) (1) Each pharmaceutical company shall establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the ‘‘Compliance Program Guidance for Pharmaceutical Manufacturers’’ and with the ‘‘Code on Interactions with Health Care Professionals.’’

(2) Notwithstanding paragraph (1), drug samples given to physicians and healthcare professionals intended for free distribution to patients, financial support for continuing medical education forums, and financial support for health educational scholarships are exempt from any limits if that support is provided in a manner that conforms to the ‘‘Compliance Program Guidance for Pharmaceutical Manufacturers’’ and the ‘‘Code on Interactions with Health Care Professionals.’’

(3) Payments made for legitimate professional services provided by a health care or medical professional, including, but not limited to, consulting, are exempt from any limits, provided that the payment does not exceed the fair market value of the services rendered, and those payments are provided in a manner that conforms to the ''Compliance Program Guidance for Pharmaceutical Manufacturers'' and with the ''Code on Interactions with Health Care Professionals.''

(e) The pharmaceutical company shall annually ~~certify~~ *declare*, in writing, that it is in compliance with both its Comprehensive Compliance Program and this chapter. The pharmaceutical company shall make its Comprehensive Compliance Program and its annual written ~~certification~~ *declaration* of compliance with the program available to the public on the pharmaceutical company's Web site and shall also provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written ~~certification~~ *declaration* of compliance may be obtained.

~~(f) Nothing in this section shall be construed to create a standard for a pharmaceutical company that is less restrictive than any otherwise applicable provision of law.~~

~~(g)~~

(f) This section shall become operative on July 1, 2005.

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